



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 15, 2018

Bob MacDonald
Agent, Scientific and Regulatory Consultants, Inc
Crosstex International Inc.
10 Ranick Road
Hauppauge, NY 11788

Subject: Notification per PRN 98-10 – Application to Add Additional Package Sizes
Product Name: Dentapure Microbiological Water Purification Cartridge
EPA Registration Number: 74245-5
Application Date: October 31, 2018
Decision Number: 545991

Dear Mr. MacDonald:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Michael Varco at (703) 347-0403 or via email at varco.michael@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Wanda G. Fuller, for".

Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

11/15/2018



INSTRUCTIONS FOR USE
[[DentaPure] [Microbiological] Water Purification [Cartridge]]
[DENTAPURE®]
[For Use As A Microbiological Dental Unit Water Purifier]
 [[Microbiological] [Dental Unit] Water Purification [Cartridge] [System]]

PLEASE SAVE THESE INSTRUCTIONS FOR FUTURE USE

Only selected information is contained on the cartridge packaging, therefore you should keep this sheet for future reference.

Active Ingredient: Iodine*.....46%
Other Ingredients.....54%
Total.....100%

*bonded to strong base anion exchange resin

Keep Out of Reach of Children

CAUTION

[In the remote event the cylinder or cartridge is broken and the iodinated resin pellets are exposed, use extreme caution.]

FIRST AID:

IF IN THE EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Have product container or label with you when calling a poison control center or doctor, or going for treatment.

See accompanying instructions for use for directions, first aid and additional precautionary statements

EPA Registration No: 74245-5 EPA Establishment No: 52252-MN-001

[company website] [company email address]

Manufactured for: Crosstex International [,Inc.]

10 Ranick Road, Hauppauge, NY 11788

[Telephone #:][Phone] (631)582-6777 [Fax:(631)582-1726] [Patents:xx[and other pending]] ©[XXXX]Crosstex International.[, Inc.]

NET CONTENTS: [Microbiological Dental Unit Water Purifier][1 cartridge]

Unit[Number]	DP365M	DP90M	DP365B	DP40B	DP365VC, DP365HP	DP365VC3 DP365HP3	DP365VC4, DP365HP4
Iodinated Resin	38.0 cc	12.0 cc	16.0 cc	4.0 cc	160.0 cc	240.0 cc	320.0cc

**PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS:
CAUTION:**

Avoid direct contact with eyes, skin and clothing. Wear protective eyewear (goggles) and gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Safety and effectiveness in children under the age of two has not been established.

ENVIRONMENTAL HAZARDS: The exposed resin pellets are toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. For guidance, contact your State Water Board or regional office of the EPA.

[NOTE: Used, undamaged cartridges and cylinders are not considered hazardous and may be wrapped in newspaper and disposed of in the regular trash.]

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN ANY
MANNER INCONSISTENT WITH ITS LABELING

DIRECTIONS FOR USE

[General Instructions and Information]

To obtain maximum bacteriological reduction, dental unit waterlines are to be cleaned with an approved dental unit waterline agent prior to initial installation of [DentaPure®] cartridges.

[General Precautions]

USES: [DentaPure®] cartridge is for use on dental unit waterlines attached to the dynamic dental instruments. Used according to labeling, this cartridge reduces bacteria from the water supplied through the instruments to a level that will meet or exceed the current ADA recommendations for water quality having a maximum of 200 cfu/ml.

[IMPORTANT!]

Use [DentaPure®] cartridge on dental unit waterlines only, not for general consumption. While the unit will perform above these limits, it is recommended that the dental unit water have a pH level of less than 8 and not have a chlorine level greater than 1 ppm. Do not use heated water. Heated water will promote the growth of bacteria and the buildup of biological film in the water line leading to the DentaPure unit. Water pressure must not exceed 45 psi.

If package seal is broken or cartridge appears dry, wrap the cartridge in newspaper and dispose of it in the trash.

Once the cartridge is in place, the supply water will pass through the cartridge's iodinated resin bed, purifying the water delivered by the dental instrument. To maintain a continuous iodine presence within the dental tubing, install a new cartridge immediately after removing the used cartridge. The cartridge must be left in place during times that the dental unit is not used (weekends, vacations, etc.).

Adherence to CDC/ADA guidelines for aseptic procedures including a 2 minute morning flush, a 20-30 second flush between patients, and hand piece sterilization must be continued after the installation of the cartridge.

[If the cartridge is used in conjunction with a bottle water system:] The bottle in water bottle systems must be emptied each night and the empty bottle replaced on the manifold. [Prior to] [or] [Before] daily use, wash the inside of the bottle and rinse thoroughly. Wipe down the outside of the cartridge, and make sure the intake end is not obstructed. Fill with fresh water each morning before its first use. [The DentaPure® DP40B cartridge must be changed after 40 liters of water usage, or if records of usage are not kept, after 60 calendar days of installation.]

Change the cartridge if the level of iodine output falls to less than 0.5 ppm. Use iodine sensitive test strips to verify performance. See the chart below for suggested change intervals. To change cartridge, follow installation instructions. Remove the used cartridge and install the new DentaPure® cartridge. Operate the dental instrument to check flow and verify that the unit is ready for use. Install a new water check-off sheet. Dispose of the old cartridge according to disposal instructions. Shut off water to dental unit when not in use.

Suggested use table:

DentaPure® Unit Size	If Water Usage Records Are Kept	If Water Usage Records are NOT Kept	If Iodine Content is Monitored
DP40B	40 Liters	60 Calendar Days	Change when iodine output falls to less than 0.5 ppm
DP90M	60 Liters	90 Calendar Days	
DP365M, DP365B, DP365VC, DP365HP, DP365VC3, DP365HP3, DP365VC4, DP365HP4	240 Liters	365 Calendar Days	

STORAGE: Store at room temperature in original packaging, away from children, pets and direct sunlight. Avoid excessive heat. Do not allow cartridge to freeze. Do not store in open or unlabeled containers.

DISPOSAL: Securely wrap cartridge in newspaper and discard in trash.

TROUBLESHOOTING

Slow or no water flows through cartridge-Make sure new cartridge was installed [properly]. Make sure air supply is turned on (maximum 45 psi). Make sure cartridge is off the bottom of the bottle. Air leak from fitting, contact your dental dealer for replacement parts. Discoloration of the tubing from blue to green or black is normal and is not a concern. [Initial dark discoloration of water is caused by release of activated carbon.] [Operate water until flow appears clear.]

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[Telephone #:] [Phone:] (631)582-6777 [or] Fax: (631)582-1726

QUESTIONS OR COMMENTS? Visit our website at www.crosstex.com [or] e-mail: crosstex@crosstex.com or call us at 1-631-582-6777. DentaPure® is a [Registered] trademark of Crosstex International.[,Inc.]

©[XXXX]Crosstex International.

{Optional language/pictures/diagrams that may appear on any panel of the carton label or in collateral literature in any combination}

[Advanced][,] [Easy to Use] [and] [Cost Effective] Clinical Water Treatment Technology.]

[How Do You Treat Your Patient Use Water?]

[How Often Are You Sanitizing Your Dental Unit Water Lines?]

[We Do Both For You]

[No More Tablets]

[No More Shocking]

[1 Full Year]

[Waterline control and CFU control in less time with no mess]

[Since 1997]

[Same technology used by NASA-Space Shuttle and International Space Station]

[Studies show that water heaters can be a source of increased biological contamination. For optimal biological purity, DentaPure® recommends not using water heaters.]

[For Use As A Microbiological Dental Unit Water Purifier]

[For dental treatment only]

[Not for consumption]

{For DP365B:}[For new installations only]

[Microbiological Water Purification Cartridge]

